K112603

NOV - 4 2011

**Access Hybritech p2PSA QC**
**510(k) Summary**

## 1.0 Submitted By:

Cindy McGuire
Senior Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: 952.368.1142
Fax: 952.368.7610

## 2.0 Date Submitted:

May 1, 2009

## 3.0 Device Name:

3.1 Trade Name
Access® Hybritech® p2PSA QC on the Access Immunoassay Systems

3.2 Common Name
Single (specified) Analyte Controls (Assayed and Unassayed)

3.3 Classification Name
Quality control material (assayed and unassayed)

## 4.0 Legally Marketed Device:

The Access Hybritech p2PSA QC claim substantial equivalence to the Access Hybritech free PSA QC on the Access Immunoassay Systems currently in commercial distribution, FDA 510(k) Number k993210

## 5.0 Device Description:

The Access Hybritech p2PSA QC are tri-level controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of [-2]proPSA isoform of Prostate Specific Antigen (PSA) using the Access Immunoassay Systems. The Access Hybritech p2PSA QC kit contains 3 X 5.0 mL bottles, one for each of the three control levels. The Access Immunoassay Systems utilize a "sandwich" immunoenzymatic method for quantitative analyte measurement.

BECKMAN COULTER

## 6.0 Intended Use:

The Access Hybritech p2PSA QC are tri-level controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of [-2]proPSA isoform of Prostate Specific Antigen (PSA) using the Access Immunoassay Systems.

## 7.0 Comparison to the Predicate:

The Access Hybritech p2PSA QC and the predicate Access Hybritech free PSA QC were compared. A comparison of similarities and differences between the two is provided in the tables below.

Similarities between the Access Hybritech p2PSA QC and Predicate Device k993210

| **Similarities to Predicate Device** | | |
|---|---|---|
| | Access Hybritech p2PSA QC | Access Hybritech free PSA QC |
| Quality Control Indications | Verify assay performance | Verify assay performance |
| Value assignment | Final concentrations are determined by value assignment using the Access Immunoassay Systems. | Final concentrations are determined by value assignment using the Access Immunoassay Systems. |
| Storage temperature after opening | 2 - 10°C | 2 - 10°C |
| Instrumentation / technology | Access Immunoassay Systems – Chemiluminescent | Access Immunoassay Systems – Chemiluminescent |
| Shelf life | 12 months | 12 months |
| Manufacturer | Beckman Coulter | Beckman Coulter |
| Control matrix | Buffered bovine serum albumin (BSA) matrix with preservatives. | Buffered bovine serum albumin (BSA) matrix with preservatives. |
| Form | Ready to use | Ready to use |

Differences between the Access Hybritech p2PSA QC and Predicate Device k993210

| **Differences to Predicate Device** | | |
|---|---|---|
| | Access Hybritech p2PSA QC | Access Hybritech free PSA QC |
| Analyte | [-2]proPSA | Free PSA |
| Control antigen source | Recombinant mammalian cell line | Seminal fluid |
| Kit configuration | Three 5.0 mL vials, 1 vial per level | Two 5.0 mL vials, 1 vial per level |
| Control Concentrations | Tri-level controls | Bi-level controls |

## 8.0 Conclusion:

The Access Hybritech p2PSA QC has been demonstrated to be equivalent to the predicate device. Based on the results of the product performance characteristics testing, these controls meet product claims and specifications.

Performance data from validation testing supports a finding of substantial equivalence to the Access Hybritech free PSA QC already in commercial distribution.

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Telephone: (952) 448-4848
Internet: www.beckmancoulter.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Beckman Coulter, Inc.
c/o Ms. Cindy McGuire
Senior Regulatory Specialist
1000 Lake Hazeltine Drive
Chaska, MN 55318

NOV 0 4 2011

Re: k112603
Trade/Device Name: Access Hybritech p2PSA QC
Regulation Number: 21 CFR§862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I (reserved)
Product Code: JJX
Dated: August 11, 2011
Received: September 07, 2011

Dear Ms. McGuire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

maria m Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): K112603

Device Name: Access®Hybritech® p2PSA QC

Indication For Use:

The Access Hybritech p2PSA QC are tri-level controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of [-2]proPSA isoform of Prostate Specific Antigen (PSA) using the Access Immunoassay Systems.

Prescription Use ___V___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112603